

REMARKS

Claims 1, 8-11, 37 and 49-53 are pending. Claims 22-24, 31 and 32 have been canceled. New claims 49-53 have been added.

Support for the amendments and new claims can be found, for example, in the Specification at p. 9 "Polymeric Scaffolds from Polymer/Ceramic Composites."

Claims 1, 8-11 and 37 have been rejected under 35 U.S.C. 102(b) as being unpatentable over Draenert (U.S. Patent No. 4,373,217). Applicants do not concede that this rejection is proper. However, in order to advance prosecution, Applicants have amended claims 1 and 37.

Amended claim 1 recites a device for tissue repair or replacement in which a first component comprises a preformed ceramic scaffold and the second component a polymer. As discussed in Applicants' specification, because the first component has a higher rate of in vivo degradation than the second component, after implantation of the device the first component degrades in vivo leaving a scaffold formed of the second component (i.e., the initial ceramic scaffold degrades, leaving a polymeric scaffold). (See page 9, "Polymeric Scaffolds from Polymer/Ceramic Composites.") The resulting polymeric scaffold has pores into which tissue can infiltrate, whereas the device, when initially implanted, does not have sufficient porosity to support tissue ingrowth.

Draenert discloses a bone cement for implanting a prosthesis in a stable fashion. The bone cement comprises particulate tricalcium phosphate. This particulate material is mixed with a prepolymer to form a moldable cement. After the cement has been hardened *in situ*, the tricalcium phosphate particles at the surface of the bone cement are gradually resorbed. Particles located on the surface of the hardened cement get absorbed and increase the contact area for bone growth. If accidentally, several particles are adjacent to each other and positioned close to the surface, channels can extend into the cement (*see* column 3 lines 1-27). Neither the

uncured bone cement nor the hardened cement in the patient comprises a preformed ceramic scaffold, and thus Applicant's claims as amended are not anticipated by Draenert.

In view of the forgoing comments and the claim amendments, Applicant respectfully requests that the Examiner withdraw the rejections of the claims. At least for the foregoing reasons, claims 1, 8-11 and 37 should be allowed.

With regard to new claim 49, Draenert does not disclose a device as claimed that is a solid preformed structure prior to implantation. Before hardening, the cement is injected into a patient's body, for example, into a cavity of a bone. This is clear throughout the specification of Draenert, and particularly at col. 8, lines 12-16, where Draenert explains that even if pressure is applied to the cement prior to injection, to remove air pockets, the cement is nonetheless forced out of a syringe and into the body in an injectable state. Thus, the bone cement is a formable non-solid mass prior to implantation.

With regard to new claim 50, the polymers discussed in Draenert are not resorbable, as required by claim 50. Instead, Draenert stresses the importance of using polymeric acrylates, which he explains are not resorbable so as to provide the implant with long term stability. (See, e.g., col. 1, lines 6-14 and col. 2, lines 23-37.)

Conclusion

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this

paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

In view of the above remarks, all pending claims are in condition for immediate allowance, and Applicants respectfully request that a notice of allowance be issued.

Please apply the fee for excess claims, as well as any other charges or credits, to deposit account 06-1050, referencing Attorney Docket No. 00167-482001.

Respectfully submitted,

Date: July 5, 2007

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